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Patentability of life and ethics

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Abstract

Patent law has relied in part on ethical considerations since its inception in Europe. Such considerations have been introduced more recently in the United States. Whereas the EU Directive on the protection on the occasion of the Human Genome Project of biotechnological inventions was intended to foster economic development in Europe, its implementation is outweighted by controversy about patenting life and commercialization of science. The confusion created must be cleared at the international level through harmonization of patent office policies preventing abusive commercial practices in the absence of inventiveness. ***To cite this article: N. Lenoir, C. R. Biologies 326 (2003).***

Résumé

Brevetabilité du vivant et éthique. Le droit des brevets s'est fondé en partie sur des considérations éthiques depuis son apparition en Europe. De telles considérations n'ont été introduites que récemment aux États-Unis. Alors que la Directive sur la protection des inventions biotechnologiques avait pour intention de favoriser le développement économique en Europe, sa mise en œuvre est contrariée par la controverse sur la brevetabilité du vivant et la commercialisation de la science. La confusion créée doit être clarifiée au niveau international par l'harmonisation des politiques des offices de brevets, en prévenant les pratiques commerciales abusives en l'absence d'inventivité. ***Pour citer cet article : N. Lenoir, C. R. Biologies 326 (2003).***

Keywords: ethics; genome; invention; life; patent law

Mots-clés : droit des brevets ; éthique ; invention ; génome ; vie

1. Patent law in historical context

Patent law can be traced back to the Republic of Venice (Statute of inventors of 1474). The first laws on patents were then passed in England (Statutes of Monopolies of 1623), and during the American and the French Revolutions, in the United States and in France (1791–1793). Of course, at that time, it would have been unheard of to patent living matter. Patent law was only set up in response to the challenges of the 'Industrial Revolution' when you could hold in your hand inventions such as machine tools. But nowadays for the first time life itself is patentable. Indeed we are moving in uncharted waters. We are entering the world of biological control and that's why patenting

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life is not only a technical issue. This is not true only regarding human genetics. Look at transgenic animals, they can produce human therapeutic substances in their milk replacing the machine tools of yesterday.

If patenting life thus raises entirely new ethical questions, it is notable that ethical considerations were taken into account in patent law long before. Especially in Europe, ethics has been present in patent law from its very beginning at two main levels.

First patent law in Europe as elsewhere was to a certain extent originally based on ethical considerations. The main justification for protecting inventions is to comply with the principle of fairness. Through patent law, society recognizes that the inventor whose intelligence allows citizens to benefit from progress deserves financial reward. As the parliamentary report to the French National Assembly which adopted the 1791 patent law says, patents are a form of social contract between the inventor and society. According to this contract, society protects on the one hand the inventor's rights; on the other hand, the inventor accepts sharing knowledge with society in making its invention available in the return of royalties to those who use it to produce industrial goods [1].

Ethics is also taken into account, in Europe especially, in so far as European patent law traditionally prohibits patent inventions whose publication or exploitation would offend "public order or morality". Such exclusion of patentability was provided for by all the numerous European treaties on the subject since the beginning of the nineteenth century. It is still mentioned in the Convention of Munich of 1973 at present in force throughout Europe (article 53a), in the EU as well as in countries not yet members of the EU such as Switzerland. Although the idea of 'public order and morality' is difficult to define as it refers to quite relative concepts, no one has ever suggested abandoning it in Europe. Provisions excluding of patentability are traditionally introduced in domestic patent laws in Europe. Their applications are rather mean. For instance at the beginning of nineteenth century a French court ruled that a feminine condom was not patentable as contrary to morality [2]. The last European legislation on patents, that's to say the 1998 directive on the legal protection of biotechnological inventions, mentions it as a motive which justifies that either Patent Offices or judges refuse granting a patent to an invention which infringes "public order and morality", in other words, ethical values. In this respect European Community law is strictly in accordance with Europe's legal and moral traditions in the field. Later I will comment on this directive which is subject to so many controversies and which is quite illustrative of the cultural, economic and even political challenges at stake. I think it important to bring up this point right now for it shows what Europe is about: it does not only have to do with the good functioning of the market since the market is greatly influenced by cultural values which can contradict the imperative of industrial competitiveness.

Things seem to be different in the US where patent legislation does not make any provision stating that inventions contrary to morality are unpatentable. The fact that such exclusions never existed in US law symbolizes the different cultural approaches in the US and in Europe towards science and technology. In the view of many, it illustrates European pessimism. For many Europeans science is not good in itself and can even be detrimental. By contrast Americans are much more confident of 'sound science'. Such cultural distinctions are still obvious nowadays. But are they as sharp as they were years ago? More and more often, politicians refer to ethics as an important factor to be taken into consideration in science policy. Two examples illustrate this.

I was struck in particular to see Bill Clinton and Tony Blair expressly refer to ethics in the press statement they made in March 2000 fixing limits on the patentability of human DNA data derived from the sequencing of the human genome. Calling for free sharing of DNA sequences among the whole community of researchers, President Clinton claimed that the human genome is the "common patrimony of humankind", an idea that refers to ethics, to justify his view that primary genetic data were not to be sold, but to be placed in the public domain and thus freely accessible to all researchers. This announcement was made in fact to support the Anglo-American public Consortium's race to be the first to sequence the human genome, and to satisfy HGP researchers who complained that their genetic data was being used for private purposes by private companies such as Celera. Craig Venter was accused of taking advantage of these data to enrich Celera's own databank. Whatever their real motivation, it's interesting to see that President Clinton and Prime Minister Blair deemed it preferable

to put forward ethical reasons, not commercial ones, to explain their opinion on patenting life.

In the same way, it is also illustrative to note that the G8's communiqué of the meeting in Okinawa in July of 2000 mentions the necessity to map the whole human genome as well as to take into "account the principles of bioethics". The communiqué stresses the "*need for a balanced and equitable intellectual property protection for gene-based inventions, based wherever possible on common practices and policies*".

I admit though that there is still quite a difference in the way patenting biotechnological inventions is dealt with in the US and in Europe. In Europe the issue of patenting life has been put on top of the political pile for several years and it now gives place to public debate almost as hot as the debate about genetically modified crops and genetically modified food.

Take a look at the way patenting life is debated in Europe ever since ethical concerns began to play such a decisive role in this debate. Specifically let's focus on the 1998 directive on the legal protection of biotechnological inventions [3] whose adoption by the European Parliament and the Council of Ministers took 10 years and which is now still subject to major criticism preventing it from being introduced into domestic law in several countries. Although it is meant to be incorporated into domestic law "not later that 30 July 2000", only a few Member States of the EU have already complied with this demand.

What about the directive, its purposes and its content? And what are the main ethical objections which it is subject to? And another question: how do we reconcile, through patent law, ethics and economics in a way that would satisfy everyone?

2. The difficult gestation of the 1998 directive on the legal protection of biotechnological inventions

Oddly enough, when a draft directive on the legal protection of biotechnological inventions was proposed by the European Commission in Brussels in 1988, it was not at all just question about ethics. The purpose of the text was exclusively industrial, since the European authorities knew how important it was to reinforce the competitiveness of European industries in biotechnology. European laboratories and industries were indeed very late to invest in the field compared to the US. Consequently it was urgent to allow European industries to fill the gap in getting patents more easily and more cheaply. This aim is beginning to be reached, although many more patents on biotechnological inventions are still being granted in the US (20 000 patents on living matter have been granted by the USPTO, many more than those granted by the EPO in Munich). These objectives are expressed in the 1998 directive, which states that "*in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable*". That is why the directive is aimed at harmonizing national legislation and the practices of the patent offices of the member states, since differences in national patent laws and practices in the field of biotechnology "*create barriers to trade and hence impede the proper functioning of the internal market*".

But soon Parliamentary discussions about the directive went from economics to ethics. In particular, Parliament expressed concern about the possibility of patenting human beings and violating human dignity since no limits were fixed, since there were no limits on inventions on human body parts or products. Patenting such inventions appeared to infringe on the traditional European principle of non commercialization of the human body. Moreover members or the Parliament wanted to protect animals and some did not want to patent transgenic animals. This all came up for the first time in 1991 and it gained momentum when Bernadine Healy – then at the head of the NIH – decided to allow Craig Venter to fill patent applications with the USPTO for the partial gene sequences obtained in his laboratory. The controversy raised by this issue was all the more influential since European researchers felt directly threatened, believing that patenting partial sequence of genes whose function is unknown would impede the free exchange of scientific information. This shows that in the discussions on the directive on patents on biotechnological inventions, ethical considerations quickly outweighed purely legal and economic concerns. The discussions were so acrimonious that the European Group of Ethics twice had to make recommendations to clarify the debate, especially about patenting human genes. Its first opinion is mentioned above. The second one is more focused on human genetics. It concerns the "ethical aspects of patenting inventions involving elements of hu-

man origin" and was made public on September 25, 1996. It essentially notes that "the traditional distinction between discovery (not patentable) and inventions (patentable) involves, in field of biotechnology, a special dimension. It also stresses the fact that if "*the human body, at the different stages of its constitution and development, as well as its elements, do not constitute patentable inventions*",… "*it does not come only from the usual conditions of patentability, but is also inspired by the ethical principle of non commercialization of the human body*."

The first version of the directive was rejected by the European Parliament, and the Commission – which is the only body that can propose Community legislation – had to submit to Parliament a new draft taking into account ethical concerns.

The result? The 1998 directive, although it was not its original aim, contains a lot of provisions based on ethics. That is why it is regarded as the first binding European legislation on bioethics which is directly mentioned in three provisions: first, implicitly referring to the principle of non commercialization of the human body, paragraph 1 of Article 5 states that "*The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions*"; second, article 6 is even more illustrative of ethical concerns since it lists the kinds of inventions which are not patentable because "*their commercial exploitation would be contrary to public order or morality*", in particular: "*processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*"; and last, article 7 confers to the European Group on Ethics the role *of evaluating* "*all ethical aspects of biotechnology*".

3. About the continuance of ethical objections against the directive

Everyone agrees that the Directive in question is a first attempt to establish a European 'code' on ethics, based on human dignity and human rights which are expressly mentioned. More than that, the directive describes practices deemed contrary to European ethical values, cloning in particular. Nevertheless this did not stop criticism against the directive. On the contrary, it grew more intense and crept outside Parliament.

The government of the Netherlands, supported by the Italians, at once challenged the text before the European Court of Justice in Luxembourg arguing that the ethical guarantees it contained were not enough.

A petition was launched by Professor Mattei, a well known French deputy specialized in the field, along with a German deputy, which gathered thousands of signatures through the Internet, among them signatures of very prominent scientists, in France in particular. Their main argument against the directive concerned the patentability of human genes. The petition notes that the human body is not "a mere commercial good".

And last, Greenpeace went before the EPO in Munich and opposed granting a patent to the University of Edinburgh on the "isolation, selection and propagation of animal transgenic stem cells". They argued that "*the patent includes humans and is not restricted to animals for it involves the creation of humans from genetically modified cells*". Consequently, in the claimant's opinion, it "*makes the genetically modified human him- or herself a patented product*". Since "*the source cells will be obtained from human embryos...*", the patent in question "*also encompasses the commercial use of normal human embryos which have not been genetically modified*". The European Group of Ethics has been asked by Romano Prodi, President of the Commission in Brussels, to give its opinion on the ethical issues of the patentability of human stem cells as provided for by the 1998 Directive.

However, the French government, which had supported the final text of the Directive, later expressed unease about President Clinton and Prime Minister Blair's announcement about the HGP. France asked the European Commission to interpret the Directive concerning the limits to be fixed on the patentability of human genes regarding the ethical implications encompassing discoveries and inventions.

Such furore against a directive just adopted by the European authorities after ten years of debate is unprecedented in EU history. European legislation had never been so radically put into question either

by member states, or by special interests groups or citizens.

What is behind all this? I think it is mainly due to the fact that biotechnology emblematically illustrates, for those who are worried by it, the blind forces of the market where money leads everything without a consideration for society's needs. Is it really so surprising to see that many of those who demonstrated in Seattle were also strongly opposed to the European directive on patents? No, not at all.

It is all very nuanced since the directive gives place to several kind of ethical concerns expressed by diverse groups and persons.

Some people fear – and they are not all doomsters – that patenting biotechnological inventions will lead to the instrumentalisation of life, especially human life. They object to patenting not only biotechnological processes but even living products themselves. This is in line with the US Supreme Court's ruling, 'Chakrabarty' of 1980 [4], and it's not new in European law either. For instance in 1991 the EPO granted after eight years of instruction a patent for a gene which encodes human relaxine although this hormone is naturally produced in women [5]. But to assert in paragraph 2 of Article 5 of the directive that "*an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element*", to assert that, makes patenting life appear even more radical. For anyone who is shy of human genetics (Catholics and Greens), patenting life is a strong economic incentive which could push ahead in particular the manipulation of human embryos. A professor of cell biology, Stuart A. Newman, along with Jeremy Rifkin proposed in 1999 to file a patent on a chimera (an embryo produced from cell nuclei and cow eggs) to illustrates the danger of contemporary practices of patenting life. This criticism is quite obvious in Greenpeace's abovementioned opposition to the patent possibly granted by the EPO on embryonic stem cells (although the University of Edinburgh as holder of the patent in question, in order to stop criticism, recently said that it only concerned non human animal stem cells). And what about the patenting of the technique set up by a Massachussets company to create cloned embryos produced from human cell nuclei and cow eggs as sources of procurement of stem cells? What about the patentability of human embryonic stem cells obtained to be cultured and possibly differentiated in the near future? This question cannot be dealt with only on the legal point of view and that's why Romano Prodi, President of the European Commission in Brussels, asked the European Group on Ethics to advise the Commission on the ethical aspects of patenting results of human stem cells research.

Patenting life is also seen as a powerful means to encourage all kinds of genetic manipulation on animals or plants which raise concerns: transgenic animals, chimeras, genetically modified crops. What is criticized by those who oppose such practices is in fact that the directive legitimizes them.

Other criticism comes from some researchers themselves being aware that the rush to patents is behind the growth of biotech, especially in the field of health. These researchers, especially academic European researchers of the public sector, are not really used to applying for patents. As was the case in American universities, such as Harvard in the 1970s, they have been taught to head the public interest first. They have not been brought around to the idea that research and economics sometimes have to go hand in hand. Their first duty is to disseminate scientific data throughout the entire scientific community. For them research is not a business. For instance, everyone remembers that monoclonal antibodies were not patented when they were discovered by researchers of the Medical Research Council in the UK. But the economic environment of research, especially in the health sector, is changing. First, pharmaceutical companies, facing an unusual number of expiring patents, are looking to life sciences for new drugs. Second, the laboratories involved in the field, especially start ups owned by shareholders, are under more and more pressure to promote the results of their research into the marketplace to get new resources for research. They do this in partnership arrangements with industrial firms. This is a complete cultural change in the traditions of the scientific community. Free knowledge-sharing has given place to patenting. This change is being taken into account in European domestic law. For instance, in France, legislation passed on 'Innovation and Research' allows researchers in the public sector to profit from their research in creating their own start ups, or in becoming shareholders of an existing biotech com-

pany. Prominent public institutions such as the Pasteur, Curie and Gustave Roussy Institutes have created start ups.

But such an approach is new and a number of European researchers complain that they're getting more and more dependent on the market. Making them pay royalties to companies holders of 'dominant patents' on genes, especially US biotech firms (and they are about 1300 compared to about 700 in all of Europe) will have negative effects, some of them say: it could affect the quality of research. For instance laboratories may now stop cross-checking samples for quality control. It could also delay the pace of research by unfairly increasing costs [6]. It seems that this debate exists also in the states among a few scientists. Researchers in particular highlight the ambiguity of the above mentioned paragraph 2 of article 5 of the Directive, which, in their view, does not protect against abusive commercial practices for it would allow the granting of patents on genetic discoveries deprived of any inventiveness (even partial sequences of genes whose function is yet unknown). The French National Bioethics Advisory Committee gave an opinion which well reflects this view; the view that the Directive accords insufficient respect to scientific interests and of the interests of humankind itself. First, the opinion stresses the fact that the Directive is not clear enough about the prohibition of patents on simple discoveries in that it does not prevent a broad interpretation of the scope of patentability. The opinion cites the example of the CCR5 gene whose sequence was integrated into a patent which claims to cover any use of the receptor in question, although it was obtained by systematic random sequencing of messenger RNA. That's to say without any inventiveness. Second, the French Committee puts forward the idea that patenting human genes in particular could infringe ethical values since "*the human genome is so connected to the nature of human beings, is so fundamental and necessary to their future welfare, that this knowledge cannot be appropriated. It must remain open to the scientific community and available to mankind as a whole*".

As I said before, the main criticism against the Directive comes from those who oppose globalization which the directive appears emblematically to symbolize. Such criticism is first directed to the human genome sequencing project. This project was originally presented by those who promoted it at the NIH level in the 1980's as the equivalent of the Landing on the Moon, a sort of biotechnological Apollo [7]. It was also compared to the conquest by pioneers in the North American colonies during the 17th and 18th centuries. Indeed scientists were supposed to act like pioneers and journey out and map the genetic frontier. But somehow this metaphor is now turning against its authors. Those who oppose patenting human genes in Europe assimilate this practice to colonization. They believe knowledge shouldn't be colonized since it is an integral part of human identity and thus belongs to humankind and not to laboratories. Raising the flag on this new discovered Land of Knowledge will not stand, that is what they say.

Outside the specific field of human genetics, which raises the most serious ethical concerns, patents on inventions derived from the genetic material of plants or animals are in the same way seen as fostering the unfair appropriation of living products which are part of nature, and simply cannot be commercially exploited. Patenting these natural products increases the risk of undermining biodiversity by stepping up the production of very specific and in the short term more profitable animal species or plants. This argument reflects concerns already expressed by non governmental organizations when the UN Convention of Rio on Biological Diversity of 1992, to which the European Community is party, was drafted. The question affects in particular third world countries, but also environmentalists and representatives of European traditional farmers and breeders. As is the case in the US of Jeremy Rifkin's association, patents are attacked because they are a major incentive to biotechnological development which may affect the planetary gene pool in an irreversible way and involves in any case increasing multinational control of the world's food supply.

4. What about now today?

Where will this ever-whirling wheel of change – I mean the trend of commercialization of science – lead us? Some of the arguments against patenting life are quite radical, if not unrealistic. Nevertheless, it is difficult to think that these arguments are all irrelevant. In Europe, it is impossible to ignore them all since they are underpinned by quite influential social forces: the Greens in Germany, the farmers in France, animal

rights activists in the UK... as well as by Churches. As I also tried to show, European academic researchers are sometimes also concerned by the business-oriented trend of genetic research.

Being on the bench prevents me from really taking part in the ongoing debate in Europe as to whether or not to modify the directive on patenting biotechnological inventions as was called for by certain politicians. I dare only say that, contrary to what is sometimes held, the 1998 directive is being misinterpreted by those who pretend that it allows patenting everything under the sun, such as gene sequences of without creativity. Controversial article 5 which allows patenting genes seems to me to exclude patentibility in such cases.

5. What should be done to clarify the confusion?

The answer is certainly not national or even only European. It is likely that during the next World Trade Organization meeting, Country representatives will face opposition against the present patent law system which is dealt with in a very elusive way regarding TRIP. This Agreement on the Trade-Related Aspects of Intellectual Property Rights, already in force, only provides that patent protection must be guaranteed for products and processes in all areas of technology. In my opinion, it is imperative to develop a more common appreciation of what could be a fair application of patent law that is understood and accepted worldwide.

Patents are irreplaceable to create dynamic competition among laboratories in providing financial reward to those who take the risk to invest in research. Nevertheless globalization makes it compulsory now to regulate patenting biotechnological inventions at the international level. I do not see how to ensure the good functioning of the market without harmonizing Patent Office policies. Everyone recognizes for instance that the scope of patents on genes was too broad and it must be also clear that simple partial sequences of genes are not patentable. Such harmonization is all the more indispensable as the principle of academic exemption which allows researchers to freely exchange scientific data is being less and less respected because of harsh competition between laboratories. Other proposals such as envisaging short-term patents in certain cases, or to set up a registration system as a means to address the problems posed by ESTs [8] deserve also to be taken into consideration. They provide in any case matter for discussion.

Another important legal, but also ethical question is to be now addressed concerning human biology and genetics. Who owns human genes? Individuals, the States, the companies which apply for patents on them or humankind (to refer to the statement of President Clinton about the HGP) [9]? The Universal Declaration on the Human Genome and Human Rights adopted by UNESCO in 1997 and endorsed by the United Nations in 1998, article 1 states that "*...In a symbolic sense, it is the heritage of humanity*". Article 4 of the same text provides that "*The human genome in its natural state shall not give rise to financial gains*", the idea being that there is an ethical duty of the international community to ensure that genetic knowledge is disseminated as widely as possible. It also implicitly refers to the distinction between patentable inventions and simple discoveries, as a fundamental distinction in the context of increasing global economic competition in biotechnology. What about the sale of personal national medical data bases (anonymized though) to a private pharmaceutical company such as in Iceland [10]? In an article about the Icelandic case, Georges Annas notes that "*similar projects are ongoing or under active discussion in the United States, the United Kingdom, Sweden and Estonia, and many others are likely to follow*". According to a deal with this company, the Icelandic government can use these data bases for planning and policy purposes, but the licensee controls access to them for commercial purposes for 12 years, which means that the data, if not patented, are in fact commercial goods. In the same way is it fair to continue, on the grounds of the principle of non commercialization of the human body, to ignore the economic interests of patients whose biological samples are meant to be commercially used? Patients whose cells provide genes that are patented are not paid for ethical reasons. Is it still justified in all cases? Is it justified to inform patients from whom are retrieved biological samples of the potential patent application on the invention derived from it, as was recommended by the European Group of Ethics in its opinion in 1996 about the then draft Directive on the legal protection of biotechnological inventions? In the United States, a patient who inherited an HIV – resis-

tant gene made claim for money when he learned that the company that owned the patent on the gene profited. Will it be ethically acceptable and economically fruitful to reward patients for participating in research and to allow profit-sharing with patients' associations, for instance, in cases research leads to patents [11]? I do not have a clear answer. I only see that associations of patients are becoming stakeholders participating more and more actively to the promotion of research.

What I do also note is that it's not just important but imperative to involve society in the debate on patenting life since life sciences make us reconsider the relationship between science and society. The 'future shock' that is being provoked by genetics and the change in the scientific practices concerns not only experts, but everyone.

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